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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,085	01/09/2002	Patricia Lynne Conway	28053/38258	6842

7590 06/23/2009  
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EXAMINER
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AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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06/23/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/889,085	<b>Applicant(s)</b> CONWAY ET AL.	
	<b>Examiner</b> Vera Afremova	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 4/16/2007 (same 3/05/2007).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 20-40, 63-75, 95, 97, 100-110, 115-125, 130-140 and 145-153 is/are pending in the application.
- 4a) Of the above claim(s) 20-40 and 63-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 95, 97, 100-110, 115-125, 130-140, 145-153 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Prosecution has been re-opened by Office of Petitions (4/16/2009).

Claims 20-40, 63-75, 77-95, 97, 100-110, 115-125, 130-140, 145-153 as amended (3/05/2007, same 4/16/2007) are presently pending.

Claims 77-95, 97, 100-110, 115-125, 130-140 and 145-153 are under examination.

Claims 20-40 and 63-75 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected subject matter. Election was made without traverse [3/03/2003 ].

### ***Claim Objections***

Claims 77-95, 97, 100-110, 115-125, 130-140 and 145-153 are objected to because of the following informalities:

The microorganisms should be identified by proper Latin names and the Latin name of microorganisms should be italicized. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

#### ***Indefinite***

Claims 77-95, 97, 100-110, 115-125, 130-140 and 145-153 as amended are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 77, 79, 81 and 88 as amended recite the use of "Bifidobacteria". Because this is a not a proper Latin name (see Exhibit A filed with the response) but a common name for some

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lactic bacteria used in fermented products, it is not clear as claimed what group of microbes is intended for the claimed composition.

Claims 77, 79, 81 and 88 as amended recite that microbes “are not in the form of spores”. It is not clear for what group of microorganisms in a microbial preparation the use of spores is intended. Clearly, the representatives of the genus of *Bifidobacterium* do not form spores. Thus, the exclusion of microbial spores appears to encompass the use of some other spore-forming bacteria that are not in a form of spores in the claimed product. Therefore, claims are indefinite and confusing.

Claim 97 recites “yeasts, lactic acid bacteria” in product limited to “Bifidobacteria” (claim 77). There is insufficient antecedent basis for this limitation in the claim.

### ***New matter***

Claims 77-95, 97, 100-110, 115-125, 130-140 and 145-153 as amended are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation that microbes “are not in the form of spores” has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus that would show possession of the concept of the use of microbes that “are not in the form of spores”.

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The generic disclosure on page 5 describes the use of various microbes including, for example: *Clostridium* and *Bacillus*, which form spores. However, generic disclosure does not describe that the final product excludes spores, if the spore-forming microbes are used. The exemplified disclosure does not describe protocol of using the spore-forming microbes and avoiding spore formation. The exemplified disclosure solely relates to the use of *Bifidobacterium* and it is known the representatives of the genus of *Bifidobacterium* do not form spores.

Thus, this is no sufficient support for the inserted limitation. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of “are not in the form of spores” is considered to be the insertion of new matter for the above reasons.

Applicant is hereby notified that the insertion of new matter into the claims has necessitated the removal of the claim rejection over US 5,143,845 (Matsuda). However, removal of new matter will result in the reinstatement of the art rejection(s).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 77-95, 97, 100-110, 115-125, 130-140 and 145-153 as amended are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/08261 in the light of evidence by US 5,714,600 (McNaught et al.).

WO 96/08261 contains identical disclosure as the previously relied upon US 6,060,050 (Brown et al.).

Claims are directed to a microbial product comprising one component such as "harvested microbes" belonging to *Bifidobacterium* wherein the "harvested microbes" have been grown/cultured on resistant starch microbes and that have improved characteristics associated with survival/recovery. Some claims are further drawn to incorporation of a second component such as resistant starch into the total microbial products, to the amounts of resistant starch in the total microbial products such as 0.1-90 % (w/) or about 10% (w/w). Some claims are further drawn to the use of various forms of resistant starch in the total products including resistant starches derived from maize, rice, barley, potatoes and including resistant starches having amylase content at least 70 %, 80% or 90%. Some claims are further drawn to incorporation of microbial products into various food, feed, pharmaceutical and bioremediation products suitable for delivery of viable microbes.

WO 96/08261 teaches a microbial preparation comprising probiotic microorganism *Bifidobacterium* and resistant starch (entire document including abstract). The cited document clearly teaches that the probiotic microorganisms are selected such that they are able to utilize the resistant starch (page 3, lines 8-12), thus, the probiotic microorganisms were grown and harvested from media containing resistant starch before incorporation into the final product. In particular embodiment, the cited document explicitly describes that probiotic microorganism

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*Bifidobacterium* is able and it has been grown on resistant starch, for example: Figure 9 or table 4 on page 19.

The cited patent discloses amounts of resistant starch in the product and/or in the microbial preparations such as 2-20 % w/w (page 4, line 15) or 10% (page 16). The cited patent teaches the use of resistant starch RS1, RS2, RS3 or RS4 which is derived from maize, rice, barley, potatoes and to the use of maize resistant starch with amylose content of more than 50% or more than 80% (page 7, lines 1-12). The phrase "more than" as related to the amylose content means "at least 90%" because the cited US 6,060,050 refers to the use of maize resistant starch disclosed in WO94/03049, which is equivalent to US 5,714,600, wherein the maize resistant starch having more than 80% of amylose includes amylose contents of "at least 90%" (see US 5,714,600 col. 2, line 67). The resistant starch in the products of WO 96/08261 are also chemically or physically treated starches by chemical modification including esterification, acidification, etc. (page 7, lines 25-35). The microbes in the products of WO 96/08261 are characterized by a stress resistance including resistance to freezing and to freeze-drying (page 4m lines 8-14).

Thus, the cited patent WO 96/08261 anticipates the claimed invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 77-95, 97, 100-110, 115-125, 130-140 and 145-153 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/08261, US 5,143,845 (Masuda), Brown et al. ("High amylose maize starch as a versalite prebiotic for use with probiotic bacteria". Food Australia 50 (12), December 1998) and US 5,714,600 (McNaught et al.).

Claims as explained above.

WO 96/08261 is relied upon as explained above for the teaching of a microbial preparation comprising probiotic microorganism *Bifidobacterium* and resistant starch (entire document including abstract). The cited document clearly teaches that the probiotic microorganisms are selected such that they are able to utilize the resistant starch (page 3, lines 8-12) and it explicitly describes that the probiotic microorganism *Bifidobacterium* has been grown on resistant starch, for example: Figure 9 or table 4 on page 19.

Further, the reference by Brown et al. is relied upon for the teaching directed to beneficial properties of resistant starch and for a clear suggestion to incorporate resistant starches into microbial preparations/products for improving robustness and viability of probiotics in gastrointestinal tract and in the food products (table 2). It is also teaches that the high amylose maize resistant starch is particularly beneficial for lactic acid bacteria because it enhances bacterial survival and stress resistance (page 607, col. 1).

The cited patent US 5,714,600 is relied upon to demonstrate that physically and/or chemically modified resistant starch (col.7, lines 13-15) including maize starch having high amylose contents of at least 40-90% (col.2, lines 63-67) are available in the prior art and they have been suggested for various compositions including foods and other industrial products (col. 1, line 24).



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Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use or to incorporate maize resistant starch into probiotic-containing products with a reasonable expectation of success in increasing survival and recovery of microbial preparations in various products because benefits of incorporations of resistant starch into probiotic compositions are known as adequately demonstrated by Brown et al. One of skill in the art would have been motivated to use high amylose maize resistant starch in microbial resistance of probiotic cultures (Brown et al.). Thus, the claimed invention as a whole was clearly *prima-facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 77-95, 97, 100-110, 115-125, 130-140 and 145-153 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of US 6,221,350 (Brown et al.).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed to microbial probiotic products comprising at least 1) probiotic microorganisms and 2) resistant starch.

The issued claims of US 6,221,350 appear to be narrower and they require 3 components in the product including microorganisms, resistant starch and oligosaccharide. However, the pending claims are open to incorporation of other nutrients or carriers because they encompass the use of food products including confectionary, biscuits, desserts or flavored drinks that do not exclude the use of oligosaccharides or fructo-oligosaccharides and, therefore, are reasonably expected to comprises at least some amounts of oligosaccharides or fructo-oligosaccharides.

Accordingly, the claimed compositions are obvious variants. Thus, the inventions as claimed are co-extensive.

### ***Response to Arguments***

Applicant's arguments with respect to claims as amended have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

June 19, 2009

/Vera Afremova/

Primary Examiner, Art Unit 1657